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## **INTRODUCTION**

Plaintiff The Procter & Gamble Company (“P&G”) submits this brief in opposition to the Motion to Preclude the Testimony of Plaintiff’s Patent Law Expert filed by Defendant Teva Pharmaceuticals USA, Inc. (“Teva”). For the reasons set forth below, P&G respectfully requests that this Court consider the expert testimony of Jerry D. Voight.

## **NATURE AND STAGE OF THE PROCEEDINGS**

In this patent infringement case, P&G contends that Teva’s generic version of P&G’s Actonel products will infringe P&G’s U.S. Patent No. 5,583,122 (the “Benedict patent”). The Benedict patent includes claims covering risedronate, the active ingredient of Actonel, which is primarily used in the treatment of osteoporosis. Teva alleges that the Benedict patent is invalid, based, in part, on obviousness-type double patenting.

The pretrial conference was held on July 13, 2006, and a bench trial has been set to commence on November 6, 2006.

## **SUMMARY OF ARGUMENT**

Teva seeks to preclude P&G’s expert, Mr. Voight, from providing testimony on the basis that Mr. Voight’s testimony includes inappropriate legal conclusions and that Mr. Voight’s expertise is superfluous in the context of a bench trial. Contrary to contentions in Teva’s motion, Mr. Voight’s testimony will properly provide guidance on the nuances of complex interference practice and procedure before the United States Patent and Trademark Office (“PTO”) that will be useful to the Court in applying the appropriate legal tests and drawing informed conclusions. Furthermore, Mr. Voight’s testimony reveals important erroneous assumptions regarding interference practice and procedure that underlie the opinions reached by Teva’s own expert.

### STATEMENT OF FACTS

The patent-in-suit, the "Benedict patent," assigned to P&G, claims chemical compositions of risedronate [2-(3-pyridyl)-1-hydroxy-ethane-1,1-diphosphonic acid]. The Benedict patent matured from parent application, Serial No. 684,543 (the "'543 application"), filed on December 21, 1984, and a continuation-in-part application, Serial No. 806,155 (the "'155 application"), filed on December 6, 1985. Subsequent to the filing of the '155 application, prosecution proceeded on a substantially normal track until about July 11, 1988, at which time P&G became aware that another patent (the "Bosies patent") had issued with claims that substantially overlapped and "interfered" with some of the claims being prosecuted in the '155 application.<sup>1</sup> In accordance with the duty of disclosure, P&G disclosed this patent to the examiner responsible for the '155 application so that an interference<sup>2</sup> could be declared and proceedings conducted to determine if the Bosies patent constituted prior art under 35 U.S.C. § 102(g) against the claims of the '155 application. Soon thereafter, on July 19, 1988, P&G requested that an interference be declared between the '155 application and the Bosies patent such that this conflict could be resolved. An interference was, in fact, declared and proceeded in due course. On June 30, 1993, the Board of Patent Appeals and Interferences issued a decision granting P&G priority of invention. Bosies appealed the decision of the Board to the Federal Circuit, which reversed the Board's decision and deemed Bosies the prior inventor of the subject matter at issue. Subsequently, the '155 application returned to prosecution at the PTO.

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<sup>1</sup> Significantly, the overlap did not involve the claims including risedronate.

<sup>2</sup> When, in the opinion of the PTO, a patent application would interfere with another pending application, or an unexpired patent, the PTO declares an "interference." 35 U.S.C. § 135(a). The Board of Patent Appeals and Interferences then determines, through a course of party proceedings, questions of priority between the respective claimed inventions in conflict and determines questions of patentability. *Id.*

Ultimately, the Benedict patent issued on December 10, 1996 and included claims directed to, *inter alia*, risedronate.

Teva bears the burden of proof on the critical issue of patent invalidity, and on January 26, 2006, it submitted the Expert Report of George R. Lenz, Ph.D. ("Lenz Report"). The Lenz Report asserted,

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submitted the Rebuttal Expert Report of Jerry D. Voight ("Voight Report") to rebut false assumptions regarding interference practice and proceedings before the PTO that underlie the opinions reached by Dr. Lenz.<sup>3</sup> Mr. Voight is a former PTO examiner and has approximately 40 years of experience in the field of patent law with particular expertise in interference practice and procedure before the PTO.

Following submission of the Voight Report, Teva declined to take Mr. Voight's deposition. Instead, on July 6, 2006, Teva filed its Motion to Preclude the Testimony of Plaintiff's Patent Law Expert, alleging that the Voight Report contained improper opinions on legal and factual issues and summarily concluded that because this is a non-jury case, Mr. Voight's testimony in regard to PTO practice and procedure could not be useful to the Court.

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<sup>3</sup> The Voight Report is attached to Defendant Teva Pharmaceuticals USA, Inc.'s Brief in Support of Its Motion to Preclude the Testimony of Plaintiff's Patent Law Expert ("Teva Brief") as Ex. A.

ARGUMENT**A. The Voight Report Reveals False Assumptions Made By Teva's Expert Regarding Practice And Procedure Before The PTO.**

Mr. Voight's testimony and opinions are relevant and useful to the Court in determining the appropriate legal test to apply in evaluating Teva's double patenting claim. Under applicable Federal Circuit precedent, there are two alternative tests for determining whether obviousness-type double patenting has occurred: the "one-way" test, which considers only whether the application claims are obvious over the patent claims, and the "two-way" test, which considers both whether the application claims are obvious over the patent claims and whether the patent claims are obvious over the application claims. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). The "two-way" test applies (a) when the patent relied upon to establish double patenting was filed after, but issued before, the patent asserted to be invalid for double patenting, provided (b) the delay in issuance of the first-filed but second-issued patent is occasioned by proceedings in the PTO, and not caused by the applicant or assignee. *See* CHISUM ON PATENTS, § 903[2][c][iv].<sup>4</sup>

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<sup>4</sup> The two-way test also requires that "an applicant could not have filed both sets of claims in one application." *In re Berg*, 140 F.3d at 1437. "[A]n applicant could have filed all of its claims in one application when the disclosure of the earlier filed application will support the claims in the later filed application." *Id.* at 1434 n.5.

A proper understanding of practice and procedure before the PTO is critical to the Court's assessment as to which test will be appropriately applied to determine Teva's claim of obviousness-type double patenting. To rebut the false assumption made by Teva's expert and to assist the Court in understanding the nuances of procedures and process before the PTO, P&G submitted the Voight Report.

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**B. The Voight Report Contains Permissible Expert Testimony That Will Educate The Court On Nuanced PTO Practice And Procedure.**

In support of its motion to preclude Mr. Voight's testimony, Teva states, "This Court permits 'patent law experts' to testify . . . only on practices and procedures in the PTO, and to do so only to educate the finder of fact on how the PTO works." Teva Brief at 3. This is precisely the purpose Mr. Voight's testimony serves.

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Despite its blanket objections to Mr. Voight's testimony, Teva concedes that courts, including this Court, "permit patent experts to testify generally about the workings of the PTO, and to 'walk through' the prosecution history in a particular case . . . ."



Teva Brief at 4. Mr. Voight's explanation of the prosecution history and interference proceedings is just such a "walk-through."

After walking through interference procedure generally and the prosecution history of the Benedict patent in particular, Mr. Voight lays out the legal background that forms the context for his opinions in this case, focusing on the "one-way" versus "two-way" tests for obviousness-type double patenting and the circumstances under which each applies. *See Voight Report at 10-11.*

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In doing so, Mr.

Voight relies upon his knowledge and experience in working for and practicing before the PTO in complex prosecution and interference procedures, the inner workings of which may not be entirely familiar even to highly experienced jurists, and certainly do not seem to be familiar to Teva's counsel and expert based on the assumptions underlying the Lenz Report. Although Teva contends that Mr. Voight's testimony about PTO process and procedure is unnecessary because this is a non-jury case and that such testimony would be "a waste of time," Teva Brief at 4-5, Teva's own confusion about PTO practice and procedure implicit in the report of its expert only highlights the value of Mr. Voight's expert testimony. Accordingly, Mr. Voight's testimony is consistent with the proper role of a testifying patent expert to "educate the finder of fact on how the PTO works," Teva Brief at 3, and will be of potential assistance to the Court in navigating the highly technical landscape of prosecution and interference practice and procedure.

**C. The Court May Determine The Weight To Be Given The Different Aspects Of Mr. Voight's Testimony.**

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Teva rightly states that, as sole arbiter of the law, the Court, not expert witnesses, may draw conclusions as to what the law is and how it should be applied. *See* Teva Brief 4-5. As Teva also hastens to point out, however, this is a non-jury case in which the Court will play both the role of interpreter of the law *and* finder of fact. Nonetheless, Teva seeks to have Mr. Voight's testimony in its entirety precluded from this case based, in part, on the inclusion of certain alleged legal conclusions in the Voight Report. Teva's argument insinuates that such opinions could somehow have an unduly prejudicial effect on the proceedings. While such an argument might carry weight were this case to be decided by a jury, the Court can easily distinguish between, on the one hand, the valuable illumination of complex prosecution and interference practice and procedure before the PTO (and the accompanying permissible reference to relevant legal tests) and, on the other hand, inappropriate legal conclusions and opinions.

**D. P&G's Submission Of An Amended Voight Report Renders Teva's Concerns Moot.**

Although P&G believes that Mr. Voight's testimony as previously submitted in the Voight Report meets the standard articulated by Teva for admission, in the interest of resolving this dispute, P&G submits herewith the Amended Rebuttal Expert Report of Jerry D. Voight ("Amended Voight Report"), which constitutes a slightly revised version of the Voight Report that excludes the ultimate legal conclusions about which Teva complains. (*See* Exhibit A attached hereto.) P&G intends at trial to limit the testimony that it elicits from Mr. Voight to the information and opinions set forth in the Amended Voight Report, and will refrain from asking Mr. Voight to offer any opinion about which test for obviousness-type double-patenting should apply. As a result, Teva's concerns about the scope of Mr. Voight's opinions are moot, and Teva should have no objection to admission of Mr. Voight's testimony.

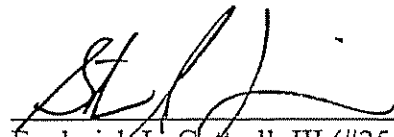
CONCLUSION

For the reasons set forth above, the testimony of Mr. Voight is proper, useful in informing the Court of the workings of complex prosecution and interference practice and procedure (so that it may properly evaluate Teva's double patenting invalidity claim), and not unduly prejudicial in this non-jury case. Therefore, P&G respectfully requests that this Court deny Teva's motion to preclude Mr. Voight's testimony as contained in the Voight Report and permit Mr. Voight to testify at trial, consistent with the opinions set forth in the Amended Voight Report submitted herewith.

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Dated: July 20, 2006

  
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IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

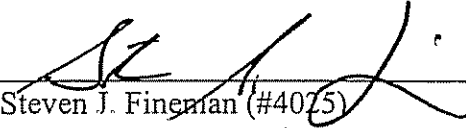
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**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

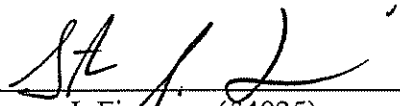
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